Trial Day 2
Volume 1 of 1
November 13, 1997

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION

GLAXO WELLCOME INC., et al. Plaintiffs v. PHARMADYNE CORPORATION, et al. Defendants	Civil Docket No. AMD-96-455 And Civil Docket No. AMD-96-1853 (Consolidated)

Baltimore, Maryland
November 13, 1997
10:10 a.m.

The above-entitled matter came on for trial before The Honorable Andre M. Davis.

A P P E A R A N C E S

On behalf of the Plaintiffs:
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Reported by: Betty Lou Walls, RPR

I N D E X

the '249 patent.

Q Was there ever any question in your mind that you were the inventor of the '249 patent?

A No, there wasn't, in that if I go back to the history of what was happening at that time, as I described yesterday, we had first of all a problem that I lost the parabens preservative and then I immediately wanted to know why was this happening, where had it gone, what was the cause of this mystery. Then I, the breakthrough was when I saw this, as I described yesterday, a cap with a black mark and the strange smell and I instigated the investigation with a microbiological colleague, found the organism, *Pseudomonas cepacia*, so I got the problem, identified the cause of the problem. And then I was the team leader at that time, the ball was firmly in my court, I wanted to find the solution to cure this problem and in order to do that I looked at the options. It was me that went through how are we going to get over this problem and it was me that came up with the idea that we should use alcohol, amongst other things, to test to see whether we could overcome the problem. I firmly believe I am the inventor, it's mine.

Q Could you describe for the Court the work that is reflected on the second page of Trial Exhibit 242? I believe the date is August 16, 1985; is that correct?

A That's correct. This is a summary on that date of the

options as I saw them, taking into account the UK situation, the U.S., and the various approaches that we could use. It's a fairly long list because there were several options I was considering.

The first of these, we knew that the organism had restricted growth when it was stored in the refrigerator, cold, so one possibility was to get the show back on the road, having come to a screeching halt. Why don't we launch the product with a four-degree restriction? It would overcome the product with the microbial contamination proliferation. The disadvantage is that, going back to the patient that has to use the product, the patient would have to store it in the refrigerator, less than ideal. Also, it may have given ranitidine an undeserved reputation for instability. The four-degree storage wouldn't have been due to ranitidine, it would be because of the bug problem. Four-degree storage was possible but not favored.

The next option on my list here is with ethanol, ether alcohol. We had at that time done testing to show that the inclusion of alcohol killed the microorganism. But the next stage was to check whether it was medically acceptable. If we have a patient with an ulcer, it's not the best thing to do to add alcohol to the medicine for treating the ulcer. We know that alcohol can irritate ulcers. So that needed to be checked out.

Also the stability, if we add another ingredient stability could be compromised, not just the ranitidine, but any other aspect of the formulation.

Then we also had to check not just using ethanol but we had a number of different attempts at preserving the syrup. We had the first attempt with three parabens and we had the, later we had the later formulation where one of the preservatives was removed. We had to decide if we go with alcohol, do we go to the original formulation or do we go to the second? That was another consideration.

And then, always aware of the fact this project had come to a screeching halt, wanting to get the show back on the road quickly, I had to move fast. So looking at timetables here, if ethanol is okay, we would set up some stability batches in mid-September, analyze after three months storage, report the results, take it to our international standards committee. This is a committee that oversees every new formulation standards that we do for the company to make sure the standards are suitable for the use throughout the Glaxo Wellcome Group, and those standards are commonly in excess of national standards.

Then that covers the UK perspective.

From the U.S., we had two choices. One was similar to the UK, we could put the NDA in with the four-degree restriction, store in the refrigerator with the same